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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/044,622 | 01/09/2002 | Olga Bandman | PF-0185-2 CON | 1927 |
| 27904 | 7590 | 10/07/2003 | EXAMINER | |
| INCYTE CORPORATION (formerly known as Incyte Genomics, Inc.) 3160 PORTER DRIVE PALO ALTO, CA 94304 | | | SAOUD, CHRISTINE J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/044,622 | BANDMAN ET AL. | |
| | Examiner | Art Unit | |
| | Christine J. Saoud | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 17-18 and 56, drawn to a protein and composition thereof, classified in at least class 530, subclass 399, for example.
- II. Claims 3-7, 9-10, 12-13 and 57, drawn to a polynucleotide, cell and recombinant method of protein production, classified in at least class 435, subclass 69.1, for example.
- III. Claim 8, drawn to a transgenic organism, classified in class 800, subclass 2, for example.
- IV. Claims 11, 31-32, 34, 36-43, drawn to an antibody, classified in class 530, subclass 387.1, for example.
- V. Claims 14-16, drawn to a method of detecting a polynucleotide in a sample, classified in at least class 536, subclass 24.31, for example.
- VI. Claim 19, drawn to a method treatment by administration of the polypeptide, classified in class 514, subclass 2, for example.
- VII. Claims 20, 23, 26 and 27, drawn to a method of screening using the polypeptide, classified in class 436, subclass 501, for example.
- VIII. Claim 21, drawn to a compound of undisclosed constitution (called an agonist), classified in class undetermined, subclass undetermined.

- IX. Claim 22, drawn to a method of treatment by administration of a compound of undisclosed constitution (called an agonist), classified in class undetermined, subclass undetermined.
- X. Claim 24, drawn to a compound of undisclosed constitution (called an antagonist), classified in class undetermined, subclass undetermined.
- XI. Claim 25, drawn to a method of treatment by administration of a compound of undisclosed constitution (called an antagonist), classified in class undetermined, subclass undetermined.
- XII. Claim 28, drawn to a method of screening utilizing the polynucleotide, classified in class 435, subclass 6, for example.
- XIII. Claim 29, drawn to a method of assessing toxicity utilizing the polynucleotide, classified in class 435, subclass 6, for example.
- XIV. Claim 30, drawn to a method of diagnosis utilizing an antibody, classified in class 435, subclass 7.1, for example.
- XV. Claims 33 and 35, drawn to a method of diagnosis by administration of an antibody, classified in class 436, subclass 547, for example.
- XVI. Claim 44, drawn to a method of detecting the polypeptide utilizing an antibody, classified in class 436, subclass 501, for example.
- XVII. Claim 45, drawn to a method of purifying a polypeptide utilizing an antibody, classified in class 530, subclass 413, for example.
- XVIII. Claims 46-55, drawn to microarrays and method of using, classified in at least class 536, subclass 23.4, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group II could be used in an entirely different manner from making the polypeptide of Group I, such as in the methods of Groups V, XIII, and/or XIV.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group II could be used in an entirely different manner from making the transgenic organism of Group III, such as in the methods of Groups V, XII, and/or XIII.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides

of Group I could be used in an entirely different manner from making the antibodies of Group IV, such as in the methods of Groups VI and/or VII.

Inventions I and (III, V, VIII-XVIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of Group I is physically and functionally distinct, have different modes of operation, different functions and different effects from the claimed compounds/organisms of Groups (III, VIII, X, and XVIII), and the polypeptide is not required for any of the recited methods of Groups (V, IX, and XI-XVIII) (i.e. not capable of use together).

Inventions I and VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group I could be used in either of the methods of Groups VI or VII.

Inventions II and (IV, VI-XI, XIV-XVII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of Group II is physically and functionally distinct, have different modes of operation, different functions and different effects from the claimed compounds of Groups (IV, VIII, and X) and the polynucleotide

of Group II is not required for any of the recited methods of Groups (VI-VII, XI, XIV-XVII).

Inventions II and (V, XII, XIII, XVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group II could be used in an entirely different method, such as a recombinant method of protein production, rather than in the methods of Groups (V, XII, XIII, XVIII).

Inventions IV and (XIV-XVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies could be used in any one of the distinct methods of Groups XIV-XVII.

Inventions IV and (III, VIII and X) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to compounds which are not disclosed as capable of use together, have different modes of operation, different functions, and/or different effects.

Inventions IV and (V-VII, IX, XI-XIII and XVIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the antibodies of Group IV are not required for any of the methods of Groups (V-VII, IX, XI-XIII and XVIII).

Inventions III and (V-VII, IX, XI-XVIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the transgenic organism is not required for any of the methods of Groups (V-VII, IX, XI-XVIII).

Inventions III and (VIII, X) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together in that the transgenic organism of Group III is not required for the compounds of Groups VIII and X.

Inventions V-VII, IX, XI-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to multiple methods

which have different modes of operation, different functions, different effects, different goals, different method steps and or/starting materials.

Inventions VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to compounds which have different modes of operation, different functions and different effects.

Inventions VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group VIII could be used to generate antibodies rather than for use in the method of Group IX.

Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group X could be used to generate antibodies rather than for use in the method of Group IX.

Inventions (VIII,X) and (V-VII, XII-XVIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together in that none of the methods of (V-VII, XII-XVIII) require the compounds of Groups VIII or X.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 703-305-

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7519. The examiner can normally be reached on Monday through Thursday, 8:00AM-2:00PM; voice mail service is available.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud